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10/596,115	05/31/2006	Joseph Chaiken	LTM.19-US-WO	2248

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EXAMINER
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SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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01/29/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

KAREN@CANADYLORTZ.COM  
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## **DETAILED ACTION**

### **Informal Matters**

1. Response, amendment and remarks filed 31 July 2009 to Office Action mailed 02 April 2009 is acknowledged and entered.
2. The assigned Examiner to the instant application (i.e., 10/596,115) at the United States Patent and Trademark Office (i.e., USPTO) has changed. To aid in correlating any papers for instant application (i.e., 10/596,115), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.
3. Examiner regrets any inconvenience because of the delay in issuing the instant Office Action that follows.

### **Claims Status**

4. Claims 1 and 16 have currently been amended.
5. Claims 1-18 are currently pending and are examined on merits.

### **Withdrawn Rejections**

6. In view of remarks and amendment filed 31 July 2009, the following objections and rejections in the office action mailed 02 April 2009 are hereby withdrawn:
  - Enablement rejection to Claims 1-18 under 35 U.S.C. §112, 1st paragraph;
  - Indefiniteness rejection to claims 1-3 and 6-18 under 35 U.S.C. §112, second paragraph;
  - Anticipatory rejection to Claims 1-3 and 6-18 under 35 U.S.C. §102 (b) as anticipated by Chaiken et al (US Patent 6,503,478) as cited in the IDS filed 25 January 2007.

### ***Claim Rejections - 35 U.S.C. § 103***

7. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

9. Claims 1-18 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Chaiken et al., (US Patent 6,503,478) as cited in the IDS filed 25 January 2007 in view of Holman et al., (2000. IR Spectroscopic Characteristics of Cell Cycle and Cell Death Probed by Synchrotron Radiation Based Fourier Transform IR Spectromicroscopy, Biopolymers (Biospectroscopy), Volume 57, Pages 329-335) and further in view of Rhiel et al (2002. Nondestructive Near-Infrared Spectroscopic Measurement of Multiple Analytes in Undiluted Samples of Serum-Based Cell Culture Media. Biotechnology and Bioengineering, Volume 77, Pages 73-82) filed as Exhibit "A" with Applicants' response on 31 July 2009.

Claims recite a method to determine the viability of living cells said introducing living cells into a container loaded with deuterated materials, wherein deuterated materials are heavy water (i.e., D<sub>2</sub>O), deuterated glucose, or deuterated amino acid and obtaining emitted vibrational spectra. Said spectra being Infra Red (i.e., IR) or Raman.

Regarding Claims 1-18, Chaiken et al teach that Raman specific agents, such as water and phospholipids, are used in a method of imaging tissue comprising administering a deuterated imaging agent (i.e., a deuterated material) and performing spectroscopy, particularly Raman spectroscopy (i.e., obtaining vibrational spectra) using a near infrared laser, so as to obtain information regarding the distribution of specific endogenous chemical species by imaging the exogenously applied deuterated agents. Chaiken et al., further teach that substituting a deuterium for a hydrogen results in lowering of the vibrational frequency by about 1.414 causing a shift of about 800 to 900 cm<sup>-1</sup> for CH bonds, and about 900 to 1000 cm<sup>-1</sup> for O-H bonds (see, for example, Abstract; Column 2, Lines 1-20 and 50-67; Column 3, Lines 1-10; Column 4, Lines 27-29 and Column 5, Lines 22-26 and 46-65, particularly Lines 46-57). Chaiken et al., clearly teach that the general class of deuterated agents provided is not limited to only

those that are listed at Column 5, Lines 47-65. Thus, Chaiken et al., teach the deuterated amino acids as well as the compounds listed in the instantly claimed Claims 4-5.

Chaiken et al.'s teachings differ from that of instantly claimed invention because Chaiken et al., are silent regarding the viability/non-viability of cells and IR spectra.

Holman et al., teach that infrared spectroscopy is used to study individual living cells and investigate changes in IR spectral features at different points in the cell cycle of said cells (Page 334, Column 2, Lines 4-18) cultured at 37 °C in minimum essential medium with Earle's salts (Gibco BRL) and nutrients (Page (Page 330, Column 1, Lines 11-14 and 21-25). Said cells manifest features which indicate that cells are undergoing various steps in the process of cell death (See Figure 4). Furthermore, the dying or dead cells manifest (abstract, Lines 1-5 and 9-13) shift in the macromolecule bands (e.g., proteins) and a shoulder at  $-1725\text{ cm}^{-1}$  which is associated with hydrogen-bonded C=O Groups and further recite that said changes have also been observed in the IR spectra of dying cells by other investigators (Page, 334, Column 1, Lines 20-29).

Rhiel et al., teach detection of vibrational spectra of a variety of analytes including glucose and glutamine in the near infrared (i.e., NIR) and infrared (i.e., IR) range (Abstract, Lines 1-11, 13-20 and 25-29. Rhiel et al., further teach NIR spectroscopy to measure glucose in undiluted samples of serum-based cell culture media (Abstract, Lines 25-29; Figures 1-3 and Page 81, Column 1, Lines 16-18 and 51-60 and Column 2, Lines 8-14). Rhiel et al., additionally teach that said information is useful to continuously monitoring the concentration of all relevant endogenous chemical species and to maintain ideal growth conditions for maximizing cell productivity (Page 81, Column 2, Lines 8-14).

The substitution of H<sub>2</sub>O with D<sub>2</sub>O is well recognized in the study/monitoring of a particular substrate by growing cells in a culture in the pertinent art of cellular physiology. Accordingly, teachings of each of Chaiken et al., Holman et al., and Rhiel et al., when taken together would allow a person of ordinary skill to obtain a method to determine the viability of living cells. Said method comprising introducing living cells into a container loaded with deuterated materials, wherein deuterated materials are either heavy water (i.e., D<sub>2</sub>O), or deuterated amino acid and obtaining emitted vibrational spectra, wherein said spectra are IR, or Raman.

One having ordinary skill in the art at the time of claimed invention would have been motivated to modify/ combine/ incorporate in the method of Chaiken et al., teachings from each one of Holman et

al., and Rhiel et al., to obtain a method to determine the viability of living cells. Said method comprising introducing living cells into a container loaded with deuterated materials, wherein deuterated materials are either heavy water (i.e., D<sub>2</sub>O), or deuterated amino acid and obtaining emitted vibrational spectra, wherein said spectra are IR or Raman; because Holman et al., teach a method to study individual living cells and investigate changes in IR spectral features at different points in the cell cycle of said cells that are undergoing various steps in the process of cell death and Rhiel et al., teach detection of vibrational spectra of a variety of analytes including glucose and glutamine in the near infrared and infrared range. Rhiel et al., further teach that said information is useful to continuous monitoring the concentration of all relevant endogenous chemical species and to maintain ideal growth conditions for maximizing cell productivity. Please note the cell growth is a manifestation of cell viability.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to modify/ combine/ incorporate in the method of Chaiken et al., teachings from each one of Holman et al., and Rhiel et al., to obtain a method to determine the viability of living cells; because Holman et al., investigate changes in IR spectral features at different points in the cell cycle of said cells that are undergoing various steps in the process of cell death and Rhiel et al., teach that the information on the vibration spectra (i.e., IR or NIR) of a variety of nutrients (e.g., glucose and glutamine) in a cell culture medium with growing cells is useful to non-invasive monitoring of nutrient components and cell growth (i.e., cell viability). It is also *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art” as discussed *supra* (*In re Chekhovian*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted)).

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

## Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR §1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR §1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. No Claims are allowed for afore-mentioned reasons.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Kailash C Srivastava/  
Examiner, Art Unit 1657

Kailash C. Srivastava  
Patent Examiner  
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(571) 272-0923

17 January 2010

/JON P WEBER/  
Supervisory Patent Examiner, Art Unit 1657